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in a Randomized Controlled Trial

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13. ABSTRACT (Maximum 200 Words) This 3-arm randomized controlled trial evaluates the efficacy of a CD-ROM based multimedia prostate cancer education system (PIES) developed by our research group. PIES is an educational software that provides patients with information about prostate cancer and its treatment through an intuitive interface, using video, animation, text, and voice-over text. All text is tailored to a person's information seeking preference (i.e., high versus low monitors). Participants (N = 891) are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer (Group 1); b) PIES software without tailoring component (Group 2); c) and PIES software with tailoring component (Group 3). Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for three main comparisons: it evaluates the efficacy of the multimedia intervention against traditional print materials or standard care; it evaluates the influence of tailoring versus not tailoring information within a multimedia context; and, it allows for an evaluation of the moderating effect of monitoring on the efficacy of the intervention groups.				
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Introduction: Despite advances in treatment, uniform treatment recommendations for localized prostate cancer have yet to emerge. Consequently, men with this diagnosis are faced with a complex set of disease information and treatment challenges as they select a treatment option (Diefenbach, et al., 2002). To educate patients about prostate cancer and its treatment and to ease their decisional burden, we have developed an innovative CD-ROM based multimedia prostate cancer interactive education system (PIES;

<http://www.temple.edu/imits/pies.htm>). The development of the software has been guided by our cognitive-affective, self-regulation theoretical framework (Diefenbach & Leventhal, 1996; Miller & Diefenbach, 1998). PIES uses the metaphor of a health center. Patients can explore various rooms to interactively obtain treatment and disease information. PIES goes beyond the inclusion of text, video, audio, and animation, by providing a unique intelligent expert system that tailors text information to the patient's information seeking preferences (high vs. low monitoring; Miller, 1996; Miller & Diefenbach, 1998). Research has identified high monitors as information seeking and being more distressed compared to low monitors, who are classified as information distracting and being less distressed.

This 3-arm randomized controlled trial evaluates the efficacy of PIES. Participants are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer (Group 1); b) PIES software without tailoring component (Group 2); c) and PIES software with tailoring component (Group 3). Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for three main comparisons: it evaluates the efficacy of the multimedia intervention against traditional print materials or standard care; it evaluates the influence of tailoring versus not tailoring information within a multimedia context; and, it allows for an evaluation of the moderating effect of monitoring on the efficacy of the intervention groups.

Body: Task 1 of the approved SOW required obtaining IRB clearance from Fox Chase Cancer Center and the US Army Medical Research and Materiel Command. Local clearance through the Research Review Committee and the IRB was obtained expediently. Approval through the USAMRMC was obtained in June 2004. While waiting for IRB approval through USAMRMC we accomplished Tasks 2 and 3 of the SOW: we met with the Director of the Resource and Education Center Linda Fleisher, MPH and Cancer Information Specialists to discuss implementation of the study. As a result, two multimedia capable personal computers equipped with earphones in semi-private workstations have been made available for study purposes. In addition we obtained all necessary copies of the study brochures from the National Cancer Institute brochures for standard care group: 297 copies of "Understanding Treatment Choices for Prostate Cancer;" and 297 copies of "What You Need to Know About Prostate Cancer." Finally, we met with the statistician to establish a randomization scheme and refined study measures.

As we had more time than anticipated we were able to make a number of modifications and enhancements to PIES that were not described in the SOW but that will enhance the usability of the program.

Key accomplishments in this area were as follows:

- 1) In preparation for the trial, we conducted usability testing with N = 10 patients at FCCC (n = 7) and Temple University (n = 3). Based on the feedback from these patients we developed and pilot tested a pointing device training program to help novice computer users handle a mouse. We also changed some of the visual interface, such as enlarging or changing some of the icons used to navigate the program.
- 2) We enhanced the content of the PIES program by adding an "Introduction" book to the library that provides an overview of prostate cancer and explains the most common treatment options. This book also gives an overview of the potential risks, benefits, side effects, and approximate recovery times for each of the three most common treatment options. Different versions of this book appropriate for high and low monitor information seeking styles were also created.
- 3) We created video footage of Dr. Miyamoto of Temple University's radiation department discussing conventional radiation therapy. This involved video taping Dr. Miyamoto, editing the footage, and integrating it into the existing program. We created similar footage of Dr. Marilyn Tseng, an epidemiologist at FCCC with interest in nutrition, who explains the role of diet in prostate cancer prevention and addresses commonly asked questions about nutrition during treatment.
- 4) Focus groups with spouses of prostate cancer patients were held to evaluate PIES. It became clear that there was a great need among spouses and partners for dedicated disease and treatment information. In response to this need we videotaped and edited a spouse/partner support group and integrated it into the program. We also created a dedicated "room" for spouses/partners as a focal point to learn about the disease.
- 5) Our statistical collaborators developed a randomization scheme to ensure that patients will have an equal chance to be randomized into one of the three treatment arms.
- 6) We made modifications to the PIES program, creating a version of the software that disabled the tailoring component.
- 7) We made copies of the CD-ROM to adequately supply each patient work station.

To date, we have enrolled seven patients into the RCT. As of October 1, 2004, I have taken on a new position in the Department of Urology at Mount Sinai School of Medicine in New York. The newly established Deane Prostate Health and Research Center is the centerpiece of the Urology Department's effort to expand its research base. New treatment and consultation facilities make the Center uniquely suited for the conduct of this research. The clinic space includes two semi-private multimedia capable workstations that will be used to evaluate PIES. The Department of Urology has an expanding practice and sees approximately 45-50 newly diagnosed prostate cancer patients. The minority patient proportion is in excess of 20% and is the result of outreach activities to nearby minority populations. Thus, MSSM research environment is excellent for the conduct of the described research. Currently, IRB approval

from Mount Sinai School of Medicine is imminent and we are awaiting clearance from USAMRMC regarding this transfer.

Key Research Accomplishments:

- Obtained regulatory clearance from FCCC and USAMRMC
- Preparation of study site
- Refinement of measures
- Expansion and refinement of multimedia program
- Enrollment of seven study participants

Reportable Outcomes: We have published one paper on PIES:

Diefenbach MA, Butz BP. A Multimedia Interactive Education System for Prostate Cancer Patients: Development and Preliminary Evaluation. J Med Internet Res 2004; 6(1) e3.
www.jmir.org

Conclusions: Despite a delay in regulatory approval we have achieved the year 1 goals as detailed in the SOW and are well underway to conduct the proposed study. The transfer from FCCC to MSSM will benefit the project, as it will ensure a higher minority enrollment, which in turn will increase the generalizability of the study results.

References: None

Appendices: None